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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,081	09/12/2003	Benjamin J. Feldman	12008.32USD1	9809

23552 7590 08/01/2006

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EXAMINER

NGUYEN, DONGHAI D

ART UNIT	PAPER NUMBER
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3729

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/662,081	Applicant(s) FELDMAN ET AL.	
	Examiner Donghai D. Nguyen	Art Unit 3729	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5 and 18-29 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1,4,5 and 18-29 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment filed on June 08, 2006 has been considered and made of record.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 4, 5, 18-21, 23-25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,708,247 to McAleer et al in view of US Patent 6,071,391 to Gotoh et al.

Regarding claims 1 and 23, McAleer et al disclose a method of manufacturing test sensor the method comprising: applying a plurality of working electrodes (14'/14) on a substrate (10); applying a plurality of counter electrodes (16/15) on the substrate; positioning a spacer layer (18) over the substrate and the working and counter electrodes; overlaying the spacer layer (18) with a second substrate (23); creating a sample chamber region (see Col. 6, lines 1-5) comprising a plurality of connected sample chambers (note the removal of the spacer to uncover the tips of the electrodes defined the chambers on the same substrate) between the substrate having the electrodes and the second substrate (see, Figs. 1A and 2); and separating a plurality of, electrochemical sensors, each electrochemical sensor comprising at least one working electrode planar with at least one counter electrode, and at least one sample chamber (Col. 6, lines, 15-17).

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McAleer et al do not teach the substrates having generally a similar length and width and the volume of the sample chamber. Gotoh et al teach the substrates (see Col. 3, lines 62-65) each having generally a similar length and width (see Fig. 6) and the sample chamber (8, see Gotoh's Fig. 3) having a volume of no more than about 1 microliter (0.5-10 microliter, see Col. 5, lines 37-38). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify invention of McAleer et al by utilize the substrates having similar length and with and the volume of the sample chamber as taught and suggested by Gotoh et al (see Gotoh's Col. 1, lines 53-58) in order to obtain a desired sensor structure for measuring and analyzing of blood sample, etc. (Col. 2, lines 21-23).

Regarding claim 4, McAleer et al do not teach the adhesive. Gotoh's teach the adhesive (100-500 micrometer in thickness) over the substrate having the electrodes (See Col. 5, lines 51-57) for reducing cost in manufacturing the sensor (see Col. 2, lines 19-21). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the invention of McAleer et al to utilize an adhesive layer for bonding the two substrates together as to by Gotoh et al.

The limitations of claims 5 and 20 are also met as set forth above.

Regarding claims 18 and 19, McAleer et al disclose the step of applying a plurality of working electrodes on a substrate by printing, screen printing or ink jet printing (See Col. 5, lines 53-67).

Regarding claims 24 and 27, McAleer et al disclose a method of manufacturing test sensor the method comprising: applying a plurality of working electrodes (14'/14) on a substrate (10); applying a plurality of counter electrodes (16/15) on the substrate; positioning a spacer layer (18) over the substrate and the counter and working electrodes; overlaying the spacer layer (18) with a second substrate (23); creating a sample chamber region (see Col. 6, lines 1-5) comprising a plurality of connected sample chambers (note the removal of the spacer to uncover the tips of the electrodes defined the chambers on the same substrate) between the substrate having the electrodes and the second substrate (see, Figs. 1A and 2); and separating a plurality of, electrochemical sensors, each electrochemical sensor comprising at least one working electrode planar with at least one counter electrode, and at least one sample chamber (Col. 6, lines, 15-17). McAleer et al do not teach the forming of indicator electrodes on one of the substrates, which having generally a similar length and width and the volume of the sample chamber. Gotoh et al teach the forming of indicator electrodes (6 or 7) on one of the substrates (see Col. 3, lines 62-65) each having generally a similar length and width (see Fig. 6) and the sample chamber (8, see Gotoh's Fig. 3) having a volume of no more than about 1 microliter (0.5-10 microliter, see Col. 5, lines 37-38). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify invention of McAleer et al by the teaching of forming the indicator electrodes on one of the substrates having similar length and with and the volume of the sample chamber as taught and suggested by Gotoh et al (see Gotoh's Col. 1, lines 53-58) in order to obtain a desired sensor structure for measuring and analyzing of blood sample, etc. (Col. 2, lines 21-23).

Regarding claims 21 and 25, McAleer et al disclose removing a portion (to expose the layer 16 and contact 11-13) of the spacer before the position it over the substrate having electrodes thereon (see Col.3, lines 34-36). Further, Gotoh et al also teach the removing a portion of the spacer (5 or 7, see Figs. 3 and 6).

4. Claims 22, 26, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over McAleer et al in view of Gotoh et al.

Regarding claims 22 and 26, McAleer/Gotoh et al do not disclose the removing a portion of the spacer after the step of disposing the spacer between the substrates. It would have been obvious matter of design choice to a person of ordinary skill in the art at the time the invention was made to remove a portion of spacer to form a sample chamber between the first and second substrates after the spacer being disposed between the substrates. Since Applicants have not disclosed that the particular portion of the spacer being removed after the disposing the spacer on the first or second substrate would require for a particular purpose, or solve a stated problem, and it appears that the invention would perform equally well with the teaching of the prior art and references (see McAleer Col. 6, lines 15-17 or Gotoh's Figs. 3 and 6).

Regarding claims 28 and 29 the prior arts do not teach the exact size of the sample chamber such as 0.25 microliter. It would have been obvious matter of design choice to form the particular sample chamber size and shape configurations as recited in claims 28 and 29. Since such modification such as change in size or shape involve a mere change in size of the

component and is generally recognized as being within the level of ordinary skill in the art, etc., see *In Re Rose* 105 USPQ237 (CCPA 1995).

Response to Arguments

5. Applicant's arguments filed June 08, 2006 have been fully considered but they are not persuasive. Applicants argue that McAleer et al does not disclose, "one sample region contains a plurality of connected sample chambers" ("Remarks" page 6, last paragraph). The Examiner disagrees because McAleer et al do not limit to one sample chamber. In fact, they create a number of chambers within a sample region for depositing the sample into the chambers by removing the spacer layer (18) that cover the tips of the electrodes (16) and form a channel at the end of the substrate (10) that connected to the tips of the electrodes (16, see Fig. 1A). Further, it's noted that the sample chambers are formed on the same substrate, which means they are being connected by means of the substrate.

In response to applicant's argument that there is no suggestion to combine the references (see "Remarks" page 7, last paragraph), the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Gotoh et al disclose the sample volume capable of containing at least 0.5 microliter well within the range as claimed by the present invention (see claims 7, 23, 24 and 27). Further, it is well known one having ordinary skill in the art to

modify the invention of McAleer et al by incorporated the structural of Gotoh' sensor to manufacture an electrochemical sensor that require as small as possible an amount sample especially in analysis of blood.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "an indicator electrode is use to determined when the measurement zone or sample chamber has been filled") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donghai D. Nguyen whose telephone number is (571)-272-4566. The examiner can normally be reached on Monday-Friday (9:00-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter D. Vo can be reached on (571)-272-4690. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DN

July 25, 2006


MINH TRINH
PRIMARY EXAMINER